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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,030	02/02/2004	Yasuhiko Munakata	0760-0329P	7791

2292 7590 09/19/2005

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/768,030

Applicant(s)

MUNAKATA ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/28/04; 11/15/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence Alignment.

S.S.

DETAILED ACTION

1. Applicant's election of Group I, claims 1-10, filed April 29, 2005 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, the restriction requirement is deemed proper and made FINAL. Claims 1-8 are under examination. Claims 9-14 are withdrawn from consideration, being drawn to non-elected subject matter.

Claim Language

2. It is noted that the claims refer to SEQ ID NO: 1 "in SEQUENCE LISTING". It is suggested that the claims be amended to delete this unnecessary and redundant phrase ("in SEQUENCE LISTING") because SEQ ID NO: 1 is the only SEQ ID NO: 1 in the specification and sequence listing.

Specification

3. The specification is objected to for the following minor informality: The priority information on the first page of the specification should be preceded by the title. Correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a receptor that binds to human parvovirus

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B19. This receptor is a product of nature, constituting non-statutory subject matter. Suggested language to overcome this rejection is "An isolated receptor" or "A purified receptor".

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a receptor for human parvovirus B19, consisting essentially of a protein having the amino acid sequence shown in SEQ ID NO: 1, or a protein having the same amino acid sequence shown in SEQ ID NO: 1 except that a small number of amino acid residues are substituted or deleted, or a small number of amino acid residues are inserted or added, which protein binds to human parvovirus B19. With regard to the embodiment of mutant receptors, the claims encompass a large genus of proteins that bind human parvovirus B19. Applicant has not adequately demonstrated possession of this large genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making

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the claimed product, or any combination thereof. In this case, the insufficient factor present in the claim is a partial structure in the form of a description of possible mutations, or a recitation of percent identity along with a function. There is not an adequate identification of any particular portion of the structure that must be conserved in order for the mutant receptor to bind B19.

Applicant has not described which amino acids are to be substituted, deleted or added within the 732-amino acid sequence. If one were to substitute, delete or add any amino acid, in any amount within the meaning of "small", and at any location(s), the possibilities would be enormous.

Applicant has failed to adequately define or demonstrate an embodiment of a "small number" of amino acid changes. While the claims do recite a function that the mutants must retain, binding human parvovirus B19, the lack of a structure/function correlation does not put Applicant in possession of the large genus claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. It is suggested that references to ambiguous mutations and percent identity be removed from the claims to overcome this rejection.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method

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of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived.

6. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 8 is drawn to an agent comprising parvovirus B19 receptor, capable of suppressing infection in a human. The breadth of this claim is unreasonable, encompassing a preventative measure for human infection with parvovirus. The nature of the invention is prevention of parvovirus infection. The state of the art regarding parvovirus B19 prevention is that there is no vaccine or medicine to prevent the infection. The CDC reports that only the symptoms are treatable (CDC, (2005) Respiratory and Enteric Viruses Branch, four pages, available from the official CDC website, see PTO-892). Heegaard *et al.* (*Clinical Microbiology*, 2002, 15(3):485-505, "Heegaard") reports that while B19 is the only member of the *Erythrovirus* genus, similar animal viruses that infect primates are being used in the animal models (page 498, column 1). Heegaard reports that clinical trials with a vaccine candidate comprising the VP1 and VP2 capsid proteins along with MF59C.1 adjuvant were showing promising results. It is the examiner's position that at the time of the invention, it was not known if the capsid vaccine candidate could actually prevent human parvovirus infection. Given the lack of knowledge about parvovirus protection with parvovirus capsid

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proteins, the level of predictability at the time of the instant invention was low, especially since the instant composition is a receptor and not capsid protein, as in the candidate vaccine described by Heegaard. The level of skill in the art is high, evidenced by the CDC report and Heegaard (PhD and MD). There are no working examples or guidance for preventing parvovirus infection. In order to enable a preventative pharmaceutical for humans, challenge experiments in an acceptable animal model are required. In view of the breadth of the claims, the state of the art, the nature of the invention, the lack of predictability, the high level of skill in the art, the lack of guidance and the lack of working examples, the claimed receptor is not enabled for suppressing infection.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "small" and "several" in claims 1-8, respectively, are relative terms that render the claims indefinite. The terms "small" and "several" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuiver *et al.*

(*Journal of Experimental Medicine*, 1990, 172:1049-1054, “Stuiver”). The claims are drawn to a receptor for human parvovirus B19, consisting essentially of a protein having the amino acid sequence shown in SEQ ID NO: 1. (Note that the claims are also drawn to an embodiment wherein the protein comprising an amino acid as shown in SEQ ID NO: 1 except that a small number of amino acid residues are substituted or deleted, or a small number of amino acid residues are inserted or added, which protein binds to human parvovirus B19. This embodiment does not meet the written description requirements, as addressed above. Therefore, this embodiment is not included in this art rejection.)

Stuiver discloses the autoantigen Ku, having a molecular weight of 80 kD (abstract and page 1049, first column, second paragraph). The Ku80 protein is the same protein as instantly claimed. Although the name is different, the identity and sequence of the protein is the same protein that Applicant has discovered as the receptor for human parvovirus B19. While the discovery of the relationship between parvovirus and the claimed protein may be novel, the claims are directed to the protein. Any properties associated with the protein are inherent. In this case, Applicant is claiming the exact same protein as Stuiver, evidenced by SEQ ID NO: 1 which is a 100% match with Ku80 (see attached sequence alignment). Stuiver’s protein is expected to have the same properties as Applicant’s protein. Therefore, the claims are anticipated by Stuiver.

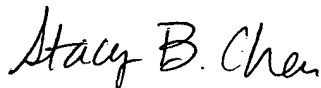
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Conclusion

9. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
September 14, 2005

GenCore version 5.1.6
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OM protein - protein search, using sw model

Run on: August 17, 2005, 20:12:52 / Search time 44 Seconds
(without alignments)
1600.697 Million cell updates/sec

Title: US-10-768-030-1
Perfect score: 3761
Sequence: 1 MVRSGNKAAYVLCMDVGFTM.....GDTAAVPEGGDVDDLLDMI 732

Scoring table: BLOSUM62
Gapop 10.0, Gapext 0.5

Searched: 283416 seqs, 96216763 residues
Total number of hits satisfying chosen parameters: 283416

Minimum DB seq length: 0
Maximum DB seq length: 2000000000
Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database: PIR_79:.*
1: pir1.*
2: pir2.*
3: pir3.*
4: pir4.*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	ID	Description
1	3761	100.0	732	2 A32626	Ku antigen 80K cha
2	2971	79.0	732	2 J06099	Ku autoantigen 80k
3	2893	76.9	732	2 S26303	Ku autoantigen 80K
4	459	12.2	707	2 G96520	protein F21D18.26
5	294.5	7.8	728	2 S43606	R07E5.8 protein (c
6	175	4.7	595	2 A43534	Lupus autoantigen
7	161.5	4.3	600	2 S65788	Ku antigen 70K cha
8	150.5	4.0	629	2 S54567	hypothetical prote
9	146.5	3.9	1055	2 H64577	type I restriction
10	145	3.9	607	2 T40906	probable ATP-depen
11	143.5	3.8	1356	2 S32763	kinectin 1 - human
12	142	3.8	602	2 S54591	DNA-binding factor
13	141	3.7	1939	2 T18372	repeat organellar
14	138	3.7	1300	2 I53799	CGI protein - huma
15	135.5	3.6	2094	2 S33124	tpi protein - huma
16	135	3.6	1496	2 T00499	probable retroelem
17	134	3.6	1927	2 G64585	cag pathogenicity
18	134	3.6	2166	2 G70163	hypothetical prote
19	132.5	3.5	871	2 E97035	DNA polymerase I,
20	132	3.5	1440	2 T33813	hypothetical prote
21	132	3.5	1642	2 T08880	NMDA receptor-bind
22	131	3.5	609	2 A30894	70K thyroid autoan
23	131	3.5	950	2 A71655	hypothetical prote
24	129	3.4	607	2 D86305	hypothetical prote
25	129	3.4	1087	2 T30330	gelsolin-related p
26	129	3.4	1538	2 T29095	cardiac muscle fac
27	127.5	3.4	990	2 H88733	protein F32E10.3 [
28	127	3.4	904	2 T03806	hypothetical prote
29	127	3.4	1837	2 T41023	probable nuclear p

ALIGNMENTS

RESULT 1

A32626

Ku antigen 80K chain - human

N;Alternate names: CTC 85 protein; DNA-dependent ATPase 83k chain; Ku autoantigen; nucl

C;Species: Homo sapiens (man)

C;Date: 21-May-1990 #sequence revision 21-May-1990 #text change 09-Jul-2004

C;Accession: A35051; A32626; JH0322; A39235; C42397; S54273; A54197

R;Mimori, T.; Ohosone, Y.; Hama, N.; Suwa, A.; Akizuki, M.; Homma, M.; Griffith, A.J.; J

Proc. Natl. Acad. Sci. U.S.A. 87, 1777-1781, 1990

A;Title: Isolation and characterization of cDNA encoding the 80-kDa subunit protein of

lap syndrome.

A;Reference number: A35051; UID:90175380; PMID:2308937

A;Accession: A35051

A;Status: preliminary

A;Molecule type: mRNA

A;Residues: 1-732 <MIM>

A;Cross-references: UNIPROT:P13010; GB:M30938; NID:g186793; PIDN:AAA36154.1; PID:g30709

R;Yanave, M.; Wen, J.; Ayala, A.; Cook, R.

J. Biol. Chem. 264, 13407-13411, 1989

A;Title: cDNA-derived amino acid sequence of the 86-kDa subunit of the Ku antigen.

A;Reference number: A32626; UID:89340410; PMID:2760028

A;Accession: A32626

A;Molecule type: mRNA

A;Residues: 1-732 <YAN>

A;Cross-references: GB:J04977; NID:g186791; PIDN:AAA59475.1; PID:g307093

R;Stuiver, M.H.; Coenjaerts, F.E.J.; van der Vliet, P.C.

J. Exp. Med. 172, 1049-1054, 1990

A;Title: The autoantigen Ku is indistinguishable from NF IV, a protein forming multimer

A;Reference number: JH0322; UID:91011245; PMID:2212941

A;Accession: JH0322

A;Molecule type: mRNA

A;Residues: 105-732 <STU>

A;Experimental source: strain Ntera 2D1

R;Knuth, M.W.; Gunderson, S.I.; Thompson, N.E.; Strasheim, L.A.; Burgess, R.R.

J. Biol. Chem. 265, 17911-17920, 1990

A;Title: Purification and characterization of proximal sequence element-binding protein

man U1 promoter.

A;Reference number: A39235; UID:91009259; PMID:2211668

A;Accession: A39235

A;Molecule type: protein

A;Residues: 2-12, 'X', 14-22 <KNU>

R;Wedrychowski, A.; Henzel, W.; Huston, L.; Paslidis, N.; Ellerson, D.; McRae, M.; Seon

J. Biol. Chem. 267, 4533-4540, 1992

A;Title: Identification of proteins binding to interferon-inducible transcriptional enh

A;Reference number: A42397; UID:92165807; PMID:1537839

A;Accession: A42397

A;Status: preliminary

A;Molecule type: protein

A;Residues: 526-565 <WED>

A;Experimental source: K562 cells

A;Note: sequence extracted from NCBI backbone (NCBI:85281)

R;Genersch, E.; Eckerskorn, C.; Lottspeich, F.; Herzog, C.; Kuehn, K.; Poeschl, E.

EMBO J. 14, 791-800, 1995
A:Title: Purification of the sequence-specific transcription factor CTCBF, involved in
A:Reference number: S54272; MUID:95188883; PMID:7882982
A:Accession: S54273
A:Status: preliminary
A:Molecule type: protein
A:Residues: 534-542 <GEN>
R: Cao, Q. P.; Pitt, S.; Leezyk, J.; Baril, E. F.
Biochemistry 33, 8548-8557, 1994
A:Title: DNA-dependent Airase from Hela cells is related to human Ku autoantigen.
A:Reference number: A54197; MUID:94304871; PMID:8031790
A:Accession: A54197
A:Molecule type: protein
A:Residues: 185-192; 316-325; 544-558; 655-660 <CAO>
C: Superfamily: Ku80 autoantigen
Keywords: dimer; DNA binding; phosphoprotein
F: 563-568/Region: nuclear location signal

```
Query Match      100.0%; Score 3761; DB 2; Length 732;
Best Local Similarity 100.0%; Pred. No. 9.66-225;
Matches 732; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 MVRSGNKAAYVLCMDVGTMSNIPGIESPPEQAKVITMFVQVFAENKDEIALVLF 60
DB 1 MVRSGNKAAYVLCMDVGTMSNIPGIESPPEQAKVITMFVQVFAENKDEIALVLF 60

QY 61 TDGTDNPLSGDQYQNTVHRHMLPDPDLLEDIESKIQPGSQQADFLDALIVSMVIOH 120
DB 61 TDGTDNPLSGDQYQNTVHRHMLPDPDLLEDIESKIQPGSQQADFLDALIVSMVIOH 120

QY 121 ETIGKPEKHHRIEFTDLSRFSKSLDIIHSLKKCDISLOPFLPSLKGESGDRGD 180
DB 121 ETIGKPEKHHRIEFTDLSRFSKSLDIIHSLKKCDISLOPFLPSLKGESGDRGD 180

QY 181 GPFRLGCHGSPFLKIGTEQKEGLEIVKVMVLSLEGEDGLDEIYSESIRKLCVPFKI 240
DB 181 GPFRLGCHGSPFLKIGTEQKEGLEIVKVMVLSLEGEDGLDEIYSESIRKLCVPFKI 240

QY 241 ERHSIHWPCBLTIGSNLSIRIAAYKSIQSRVKKTVTVDAKTLKEDIQKETVYCLND 300
DB 241 ERHSIHWPCBLTIGSNLSIRIAAYKSIQSRVKKTVTVDAKTLKEDIQKETVYCLND 300

QY 301 DETEVLKEDIQGFYRGSIVPSKVDDEOMKYSGKCFSVLGPCKSQVORRPFMGNQ 360
DB 301 DETEVLKEDIQGFYRGSIVPSKVDDEOMKYSGKCFSVLGPCKSQVORRPFMGNQ 360

QY 361 VLKVFARDDDEAAVALSLIHALLDDLVAVIYRAYDKRANPQGVAPPHIKHNYECLV 420
DB 361 VLKVFARDDDEAAVALSLIHALLDDLVAVIYRAYDKRANPQGVAPPHIKHNYECLV 420

QY 421 YVOLPFMEDLRQYMFSSLSKNSKKYAPTEAQLNAVDALIDMSLAKKDEKTDLEDLPPT 480
DB 421 YVOLPFMEDLRQYMFSSLSKNSKKYAPTEAQLNAVDALIDMSLAKKDEKTDLEDLPPT 480

QY 481 KIPNRFQRLFOCLLHRAHPREPLPIQCHIWNNMLNPPAEVTTKSIQIPLSKITLPLI 540
DB 481 KIPNRFQRLFOCLLHRAHPREPLPIQCHIWNNMLNPPAEVTTKSIQIPLSKITLPLI 540

QY 541 EAKKQDVTAQRIPODNHEDGPTAKLKTQGGAHFVSUSLAGSVTSVGSVNPANFV 600
DB 541 EAKKQDVTAQRIPODNHEDGPTAKLKTQGGAHFVSUSLAGSVTSVGSVNPANFV 600

QY 601 LVKQKASFEASNLINHIQFLDTNETPYFMKSIDCIRAFREAIKFSREORFNNFLK 660
DB 601 LVKQKASFEASNLINHIQFLDTNETPYFMKSIDCIRAFREAIKFSREORFNNFLK 660

QY 661 ALOEKVEIKOLNHFWEIVQDGIITLITKEASGSSVTAEEAKKFLAPKDPGSDTAAVFE 720
DB 661 ALOEKVEIKOLNHFWEIVQDGIITLITKEASGSSVTAEEAKKFLAPKDPGSDTAAVFE 720

QY 721 EGGDVDDLLDMI 732
DB 721 EGGDVDDLLDMI 732
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